Published in final edited form as:

J Surg Oncol. 2015 August ; 112(2): 219–224. doi:10.1002/jso.23985.

High-Quality Results of Cytoreductive Surgery and Heated Intraperitoneal Chemotherapy Perfusion for Carcinomatosis at a Low Volume Institution

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Abstract

Background and Objectives—Maximal cytoreductive surgery (CS) with heated intraperitoneal chemotherapy perfusion (HIPEC) for peritoneal carcinomatosis can improve oncologic outcomes, but is associated with significant morbidity. Whether low-volume experience with CS/HIPEC results in acceptable outcomes is unknown.

Methods—A retrospective review of all patients undergoing CS/HIPEC by a single surgeon. Experience was divided into first versus second 50 cases, and patient characteristics, operative details, and outcomes were compared.

Results—Ninety patients underwent 100 CS/HIPEC procedures (mean age 57 years, 68% female). Compared to the initial experience, the second 50 cases included more high grade tumors (68 vs. 52%) and greater disease burden (PCI 14.2 vs. 12.4). Operative times remained unchanged and mean blood loss decreased (978 vs. 684 ml). Hospital stay (mean 18.1 vs. 12.6 days), major complications (24 vs. 16%), and perioperative mortality (8 vs. 2%) declined. Overall median survival was 18 months and was longer with low grade tumors (26 vs. 16 months, $P = 0.03$).

Conclusions—Patients experienced reduced EBL, fewer major complications, and shorter hospital stay, despite having higher disease burden and higher grade tumors. This suggests that even low-volume experience with CS/HIPEC can lead to a trend in reduction of adverse perioperative events with acceptable oncologic outcomes.

Keywords

HIPEC; peritoneal carcinomatosis; peritoneal surface disease; cytoreductive surgery; chemotherapy

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Conflicts of interest: none.

The content is solely the responsibility of the authors and does not necessarily represent the official view of the National Institutes of Health.

INTRODUCTION

Peritoneal carcinomatosis or disseminated peritoneal surface disease is a common endpoint for several abdominal malignancies and has a dismal prognosis with mean survival less than 1 year [1]. Palliative surgical debulking followed by systemic chemotherapy is limited by peritoneal penetration [2], and other locoregional treatments including peritonectomy [3] and photodynamic therapy [4] have not shown reliable survival advantage given their inability to surgically remove microscopic disease. An increasing number of centers are employing cytoreductive surgery (CS) with concurrent hyperthermic intraperitoneal chemotherapy (HIPEC), aimed at treating residual microscopic disease, and have reported promising results [5–8]. This multimodal treatment approach has been shown to afford a survival advantage in patients with colorectal cancer [9,10] and gastric cancer [11] compared to historical controls, and in small prospective studies. HIPEC allows for higher intraperitoneal drug concentrations and slower washout that cannot be safely achieved via systemic therapy, which has limited peritoneal penetration. It is favored after CS because it allows exposure of drug to all peritoneal surfaces. Unfortunately, aggressive CS and HIPEC is associated with significant morbidity and mortality. Common complications such as abscesses, fistula, pneumonia, and hematologic toxicities are described in 20–65% of patients, and mortality has been reported as high as 10% [12–14]. Additionally, the higher estimated blood loss (EBL) and OR time with extensive CS has been linked to increased post-operative complications [14].

Given that patients with peritoneal carcinomatosis have no consensus treatment options and CS and HIPEC represents a substantial undertaking for the health care system, surgeon, and patient, much of the data come from centers with the highest volumes and systems built to accommodate this undertaking [8]. It is unclear whether growing experience with HIPEC at low-volume centers can produce similar results. This is important to determine as more centers and surgeons are instituting practices that offer this aggressive surgical modality for peritoneal surface malignancy. We aimed to examine our first 100 procedures for patients undergoing CS and HIPEC for peritoneal carcinomatosis, hypothesizing that surgeon experience played a significant role in morbidity and outcomes with this intervention.

MATERIALS AND METHODS

This study was approved by the Human Subjects Division of the Fred Hutchinson Cancer Research Center.

Study Design and Definitions

A retrospective cohort was created of all patients undergoing HIPEC and CS for peritoneal surface disease at the University of Washington (UW) between January 1, 2001 and June 30, 2014. Medical records were used to collect patient and tumor characteristics, intraoperative details, and postoperative morbidity and outcomes. Patient characteristics included age, performance status, preoperative nutritional status, and gender. Tumor characteristics included pathologic diagnosis, tumor grade, and primary site of disease. Operative characteristics included peritoneal carcinomatosis index [15], viscera resected, completeness of cytoreduction, operative length, transfusion requirements, and EBL. The main outcome

was overall survival. Secondary outcomes included length of ICU and total hospital stay, post-operative complications, classified using the Clavien–Dindo system [16], and 60-day readmission. Patients were followed in the UW surgical clinic at 1 and 6 months postoperatively and subsequently by their medical oncologist (often outside of UW). Long-term follow-up was continued with the senior surgeon at 6–12 monthly intervals if possible.

Preoperative Assessment

All patients were assessed in the UW surgical oncology clinic preoperatively, which included independent reviews of their pathology and cross-sectional imaging. Patients were counseled against HIPEC/CS if they lacked the fitness to undergo this procedure (ECOG >2), or their disease burden appeared significant and involved extra-abdominal metastases, significant liver involvement, multiple portions of small bowel, or mesenteric involvement prohibitive of appropriate cytoreduction.

Cytoreductive Surgery and Hyperthermic Intraperitoneal Chemotherapy

Surgical intervention was standardized. The extent of disease was assessed upon entering the peritoneal cavity using the peritoneal carcinomatosis index [17]. Next, all gross disease was removed and peritoneum stripped as safe and feasible. Completeness of cytoreduction was assessed using American Joint Committee on cancer criteria: CC0 no remaining disease; CC1 <0.25 cm residual disease; CC2 0.25–2.5 cm residual disease; CC3 >2.5 cm residual disease [18].

Hyperthermic intraperitoneal chemotherapy (HIPEC) was then administered according to our institutional protocol. Two inflow catheters were placed into the upper abdomen and an outflow catheter was placed into the pelvis. The skin was temporarily closed and perfusion circuit established. With patient and perfusate temperature constantly monitored, the circuit was heated with a target outflow temperature of 40–41°C. Chemotherapy was introduced as 30 mg of mitomycin C for the first hour and circulated, followed by a 10 mg boost for the second hour to keep drug concentration >5 ug/ml. In patients with peritoneal mesothelioma, ovarian cancer, and leiomyosarcoma, cisplatin was used instead of mitomycin C at a dose of 250 mg/m² and perfused for 1.5 hr only. Sodium thiosulfate was used for renal protection [19]. During perfusate infusion, the abdomen was manually agitated to improve drug distribution to all surfaces. Once perfusion was completed, the circuit was flushed with copious Lactated Ringers, the abdomen was re-opened, irrigated, bowel continuity reestablished when appropriate, and formal closure performed.

Statistical Analysis

Experience was divided into first versus second 50 cases. Patient, tumor, operative characteristics, and outcomes were summarized using frequency distributions for categorical variables, and mean (SD) for continuous variables. Categorical variables were compared using Pearson χ^2 statistic. Continuous variables were compared using the Student's *t*-test when normally distributed and two-sample Wilcoxon rank-sum test when not normally distributed. Kaplan–Meier survival curves, stratified by tumor grade were plotted. Time axis was in months, using date of HIPEC as time zero with survival measured to the last known date of follow-up or date of death. Cognizant of the higher frequency of high-grade tumors

in the latter half of our cohort, Cox proportional hazards to determine the association of tumor grade with survival used adjustment for cases in the second half of the cohort as an indicator variable. Group comparisons were performed using the approximate chi-square statistic for the log-rank test. All analysis was performed using STATA version 13 (STATA Corp, College Station, Texas).

RESULTS

From 2001 to 2014, 90 patients underwent 100 CS/HIPEC procedures at the University of Washington (mean age 57 ± 11 , 68% male) (Table I). Nine patients had HIPEC and CS twice and one patient had three procedures. DPAM (42%), colorectal cancer (18%), and appendiceal cancer (18%) were the most common indications, and most tumors were high grade. Sixty-eight percent ($n = 41$) of 60 patients with high grade tumors received neoadjuvant chemotherapy while only 1 of 40 with low grade tumors had pretreatment. The mean number of procedures per year increased fourfold from three per year over the first 4 years ($n = 17$) to greater than 12 per year over the last 4 years ($n = 41$) Figure 1. Colon (66%), diaphragm (48%), and small bowel (42%) were the most common resected organs (Table II). Overall rate of ileostomy or colostomy was low at 7%.

The mean PCI was 12.4 and 14.2 for the first 50 and second 50 cases, respectively, and CC0–1 was achieved in 92% of cases. Despite the higher tumor burden, operative length (median 8.0–8.5 hr, range 4.5–15 hr) remained unchanged and EBL decreased (978–684 ml). Mean ICU stay was shorter (4.1–1.4 days; median 0 days for both) as was overall hospital LOS (18.1–12.6 days; median 10–9 days).

Overall perioperative morbidity and mortality was 60 and 5%, respectively. Wound infection, intra-abdominal abscesses, delayed return of bowel function, enterocutaneous fistula, and hematologic toxicities accounted for the majority of complications. Major complications (Dindo III/IV) decreased from our initial experiences to our recent experience, (24–16%). There were four perioperative deaths in the first 50 cases, and a single perioperative death in the second 50 cases.

Median follow-up was for the entire cohort was 18 months with 48% having follow-up greater than 2 years. Overall survival at 1 and 2 years was highest in patients with DPAM and ovarian cancer (Table III). Kaplan–Meyer survival curves, stratified by tumor grade, are shown in Figure 2. Survival was worse for high-grade tumors ($P = 0.009$), with 52% of patients surviving 2 years versus 69% in low-grade tumors. The hazard for death with a high-grade tumor was not different after adjustment for cases performed in the second half of the cohort ($P = 0.054$). Patients who had more complete cytoreduction had improved 1-year overall survival: 79% when CC-0, 66% when CC-1, 29% when CC-2+ ($P = 0.022$). Median disease-free survival (DFS) for patients with appendiceal cancer was 15 months (range 3–38 months). Similarly for patients with DPAM, median DFS was 20 months (range 7–57 months).

DISCUSSION

In this series, we describe the experience of a single surgeon experienced in complex gastrointestinal surgical oncology performing CS and HIPEC at a single institution. Over the span of 100 cases, we noted reduced EBL, fewer major complications, and shorter ICU and hospital stay, despite operating on patients with higher disease burden and higher grade tumors. One- and two-year survival rates were dependent on tumor biology, but reflect rates reported at high-volume institutions. These findings suggest that CS and HIPEC can be reliably performed with comparable results at low-volume centers.

Peritoneal carcinomatosis is seldom curable [1], in part because of lack of viable systemic therapy with adequate tissue penetration. The combination of maximal surgical debulking and HIPEC to address residual microscopic disease is being increasingly applied [5,7]. Given the extensive resources and tremendous investment by patient, surgeon, and healthcare system to undertake these procedures, much care has been isolated to high volume centers, where results have been promising [8]. These groups have shown a learning curve associated with CS and HIPEC on the order of 50–200 cases [8,20,21]. Whether their results can be replicated at low volume centers where these patients often present remains to be determined.

Optimizing patient selection for CS/HIPEC is critical for success, and in our series, there were a few objective factors that changed over time. In the latter half of the cohort, more patients had ECOG = 0 (49 vs. 45, $P = 0.046$), and higher pre-op albumin, (3.8 vs. 3.5, $P = 0.009$). Ultimately, the impact of these selection factors is likely small compared to underlying tumor biology, but are nonetheless notable. Patient selection is particularly important when considering that nearly half of all patients had portions of at least 2 viscera resected. With increasing experience, we were able to achieve higher rates of CS in similar operative time with fewer viscera resected. Still, when rigorously and transparently reported, overall morbidity was over 50%, despite decreases in EBL, major complications, and LOS. These results are on par with the experience of larger centers [8].

Not surprisingly, survival is linked to the underlying primary tumor and its biology. For instance, the lower survival of patients with high versus low-grade tumors can be noted on our Kaplan–Meier curves. Because of the limited number of patients in our cohort, we did not perform extensive survival modeling beyond this, choosing instead to focus on descriptions of our experience. We noted that patients with primary peritoneal mesothelioma, appendiceal carcinoma, and ovarian cancers performed superior to their counterparts with colorectal cancer [5,22,23]. In our study, patients with DPAM as indication for CS and HIPEC had the best survival advantage, likely because of its typically more indolent behavior [24,25]. Notably, our data show 2-year survival of roughly 60% in patients with metastatic CRC which is on par or superior with reported rates of optimal systemic therapy alone (20–30% 2-year survival) [26] or resection of isolated metastases (40–60% survival at 2 years) [27].

The association between surgeon experience with a procedure and outcomes has important implications on the operative morbidity and mortality. The largest-volume study available

[8] suggests that the learning curve for CS/HIPEC is around 200 cases but draws from data of multiple surgeons. Furthermore, it may take many years for smaller-volume institutions to achieve these volumes (our first 50 cases took 8 years). However, in addition to their CS/HIPEC cases, many surgeons continue to have thriving practices in complex GI surgical oncology, refining their surgical techniques and improving perioperative care for these complex patients. Therefore, optimal case number for any individual remains unclear. While we chose to stratify our study into the first and second 50 cases, our results suggest improvement in major morbidity and perioperative outcomes even with this smaller number. This parallels similar reports of high quality despite lower volume of a particular procedure from centers and surgeons experienced in complex GI surgical oncology [28].

Acknowledging that there are many potential external (unmeasured) factors that are impacting these patients, such as continued refinement of patient selection and improvement in adjuvant therapies, we believe our results show promise for CS/HIPEC at institutions with smaller volumes.

Our study has several limitations. Our small sample size with the heterogeneity of operative indications limits the detection of power of statistical tests within subgroups. For this reason, we chose to limit our findings to descriptions of rates and frequencies rather than modeled associations and predictions of survival. In addition, due to our large referral area (which spans five states), long-term follow-up was often truncated as patients returned home and received their care from oncologists or surgeons in their community. Still our rates of nearly 90% follow-up at 1 year and 80% at 2 years reflect rates of many practicing surgeons and we believe make our results valid. More patients in the second part of the cohort had a better performance status and preoperative albumin, perhaps a surrogate for improved patient selection, which may have contributed to improved perioperative outcomes as well.

Our study shows that the increasing surgeon experience over the 13 years during which CS/HIPEC was offered has resulted in reduced patient morbidity and improved outcomes. Although partially explained by technical improvement, it also likely represents ongoing refinement in patient selection. This suggests that after passing the individual and/or institutional learning curve, outcomes on par with the highest-volume centers can be achieved.

Acknowledgments

Vlad V Simianu, MD, is supported by the National Institute of Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number T32DK070555.

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Fig. 1.

Cases per year of cytoreductive surgery and hyperthermic intraperitoneal chemotherapy for peritoneal carcinomatosis between 2001–2014*. *Data represents cases through the first 6 months of calendar year (thru June 30, 2014).

Fig. 2. Kaplan–Meier survival by tumor grade. Survival lower for high grade tumors based on log-rank test ($p = .009$).

Clinicopathologic Features and Post-Operative Outcomes of Patients Undergoing Cytoreductive Surgery and Hyperthermic Intraperitoneal Chemotherapy for Peritoneal Carcinomatosis

TABLE I

	First 50 cases		Second 50 (n)		Total		P-value ^d
	n	%	n	%	n	%	
Demographics							
Mean age, ± SD	57.6	±9.5	56.3	±11.8	57	±10.7	0.53 ^b
Male	37	74	31	62	68	68	0.20
White	46	92	48	96	94	94	0.54
ECOG = 0	45	90	49	98	94	94	0.046
Pre-operative Albumin, ± SD	3.5	±0.7	3.8	±0.3	3.6	±0.5	0.009 ^b
Indications							
DPAM	26	52	16	32	42	42	0.043
Colorectal cancer	6	12	12	24	18	18	0.12
Appendiceal cancer	9	18	9	18	18	18	0.60
Mesothelioma	7	14	6	12	13	13	0.77
Other	2	4	7	14	9	9	0.11
High Grade Tumor	26	52	34	68	60	60	0.10
Operative characteristics							
CC 2+	4	8	4	8	8	8	0.39
Mean OR time ± SD, hrs	8.9	±0.6	8.6	±0.4	8.7	±0.3	0.99 ^c
Mean EBL ± SD, mL	978	± 1,180	684	±660	825	±952	0.55 ^b
Mean products transfused ± SD, units	2	±4.4	1.4	±3.3	1.7	±3.9	0.80 ^b
Mean PCI ± SD	12.4	± 10.1	14.2	±9.1	13.3	±9.6	0.28 ^b
Postoperative outcomes							
Any complication	31	62	28	56	59	59	0.002
Major complication	12	24	8	16	20	20	0.41
Mean LOS ± SD, days	18.1	±4.0	12.6	±1.4	15.3	±2.1	0.65 ^c
Mean ICU LOS ± SD, days	4.1	±1.6	1.4	±0.34	2.7	±0.8	0.84 ^c

CC, completeness of cytoreduction; DPAM, diffuse peritoneal adenomucinosis; EBL, estimated blood loss; major complication, Dindo III/IV; OR, operating room; PCI, peritoneal carcinomatosis index; LOS, length of stay; SD, standard deviation.

^a Calculated as Pearson χ^2 unless otherwise specified.

^b Calculated using Student's *t*-test.

^c Calculated using Wilcoxon rank-sum (Mann-Whitney) test.

TABLE II

Organs Resected During Cytoreductive Surgery (in Addition to Peritonectomy)

Organ resected	First 50 cases		Second 50 (n)		Total		P-value ^a
	n	%	n	%	n	%	
Colon	35	70	31	62	66	66	0.40
Small bowel	27	54	15	30	42	42	0.02
Diaphragm	25	50	23	46	48	48	0.58
Ovaries	21	42	11	22	32	32	0.03
Spleen	17	34	10	20	27	27	0.12
Uterus	17	34	8	16	25	25	0.04
Gallbladder	12	24	16	32	28	28	0.37
Rectum	11	22	12	24	23	23	0.81
Stomach	6	12	5	10	11	11	0.75
Liver	5	10	10	20	15	15	0.16
Pancreas	4	8	8	16	12	12	0.22
Bladder	3	6	7	14	10	10	0.18
Kidney	0	0	2	4	2	2	0.15
Ileostomy	3	6	2	4	5	5	0.65
Colostomy	1	2	1	2	2	2	1

^aCalculated as Pearson χ^2 unless otherwise specified.

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TABLE III

One- and Two-Year Survival by Indication and Tumor Grade

Indication	Survival 1 year		Survival 2 year		P-value ^d
	n	%	n	%	
DPAM	32	86.5	24	70.6	0.07
Colorectal cancer	11	78.6	7	58.3	0.96
Appendiceal cancer	14	82.4	8	57.1	0.91
Mesothelioma	7	63.6	5	50	0.54
Ovarian cancer	3	100	2	66.7	0.78
Grade					0.14
Low	30	85.7	22	68.8	
High	39	73.6	24	52.2	

^a Calculated as Pearson χ^2 unless otherwise specified.